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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,030	09/06/2006	Matthew Campbell	PB60299	2558

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EXAMINER	
CUTLIFF, YATE KAI RENE	

ART UNIT	PAPER NUMBER
1621	

NOTIFICATION DATE	DELIVERY MODE
08/08/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/568,030	CAMPBELL ET AL.	
	Examiner	Art Unit	
	YATE' K. CUTLIFF	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 21-29* is/are pending in the application.

4a) Of the above claim(s) *14,21,22 and 26-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/10/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 1, claims 1-13, 23-25, in part, drawn to the compound of Formula (I) where R2 and W are non-heterocyclic ring systems, in the reply filed on May 12, 2008 is acknowledged. The traversal is on the ground(s) that the restriction is improper because unity of invention exist. Additonally, that there would not be a serious burden on the Examiner and the search can be made without a serious burden. This is not found persuasive because whether or not any particular technical feature makes a contribution over the prior art, and therefore constitutes a special technical feature, is considered with respect to novelty and inventive step. PCT Rule 13.2; A1 annex B, Part 1(b). Rule 13.2 governs the situation involving a single claim that defines alternatives (chemical or non-chemical), the so-called "Markush practice." If it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention should be reconsidered by the Examiner. PCT Rule 13.2; A1 annex B, Part 1(f) In the case of Applicant's claim 1, the Examiner found that more that one Markush alternative of the claim 1 was not novel over the prior art of Lennox (WO 99/07669), which shows a break in link between the Markush groups of the claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-13, 23-25, in part, drawn to the compound of Formula (I) where R2 and W are non-heterocyclic ring systems are under examination.

Claims 15-20 stand cancelled.

Claims 14, 21-22 and 26-29 are withdrawn.

Information Disclosure Statement

2. The information disclosure statement filed February 10, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-13 and 23-25, where R2 and W are non-heterocyclic, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8

USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The inventions of claims 1-13 and 23-25, where R2 and W are non-heterocyclic are drawn to compounds and/or pharmaceutical formulations in the form of a salt, solvate or physiologically functional derivative thereof. The specification does not provide teaching or guidance for preparing any specific solvate or physiologically functional derivate, nor the use of solvates or any physiologically functional derivative of the compounds of Formula (I), where R2 and W are non-heterocyclic.

The compounds of the present invention embrace non-heterocyclic compounds with variable groups R1, R2, R3, R4, R5, Z, W, X and Y. Even a cursory calculation of the number of compounds embraced in the instant claim 1 would result in thousands of compounds. This is of course far more compounds than the specification enables one

skilled in the art to make or use. Thus, the genus embraced in claim 1 is unduly broad and there is no teaching of any solvate or physiologically functional derivate of compounds of compositions of this large genus or guidance how to use same in methods for treating pathologies as instantly claimed.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

The state of the art is that it is not predictable whether solvates or physiologically functional derivatives will form or what their composition will be. Preparation of specific solvates or physiologically functional derivatives of any compound is a very specialized field and involves their characterization using different techniques such as infrared spectrum, XRD powder diffraction, solid state NMR etc. There is a great deal of unpredictability regarding stability of different solvates or physiologically functional derivatives of any compound in the art. Thus, in the absence of undue experimentation one cannot predict if a particular solvent will solvate any particular crystal. One cannot predict the stoichiometric of the formed solvate or physiologically functional derivatives, i.e. if one, two, or a half a molecule of solvent is added per molecule of host.

(5) The relative skill of those in the art:

The level of skill in the art is high.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided no guidance or even a single working example for preparing any specific solvate or physiologically functional derivatives of instant compounds of Formula (I). Therefore, there is no evidence that solvates or

physiologically functional derivatives of the compounds of Formula (I) exist. Thus, undue experimentation will be required to determine if any particular derivative is, in fact, a solvate or physiologically functional derivatives.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed above, particularly with regards to the formation of solvates and physiologically functional derivatives and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to select specific solvates or physiologically functional derivatives of the instant compounds with enhanced stability properties.

Claim Rejections - 35 USC § 102

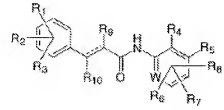
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-13, and 23-25, where R2 and W are non-heterocyclic, are rejected under 35 U.S.C. 102(b) as being anticipated by Lennox, et al. (WO 99/07669).

7. The rejected claims cover, inter alia, the compound of Formula (I), and the pharmaceutical formulations comprising the compounds of Formula (I).

Lennox et al. discloses the following compound:



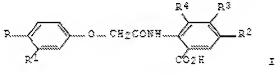
(I)

The compound anticipates the claims when W = carbon; R1, R2 and R3 are independently, hydrogen, halogen, alkoxy or alkyl; R4 = COOH; R5, R6, R9 & R10 = H; R7 & R8 are H or halogen, such as in Examples 15, 19, 25 and 45 of the reference.

8. Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Jolanta et al. (Acta Poloniae Pharmaceutica, 1979) (abstract)

9. The rejected clams cover, inter alia, the compound of Formula (I) where R2 is selected form the group set out in claim 5.

10. Jolanta et al. disclosed the following compound:



I

The compound anticipates the claims where R, R2 & R4 = H, R1 = CH_3, R3 = Cl.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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